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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/127,624	08/03/1998	F. ABEL PONCE DE LEON	002076-007	1506

7590 05/15/2003

PILLSBURY WINTHROP LLP
1600 TYSONS BOULVARD
MCLEAN, VA 22102

EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/127,624	PONCE DE LEON ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7,8,30,31,33-35,37,39,40 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7,8,30,31,33-35,37,39,40 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1632.

The amendment filed 3-3-03, paper number 26, has been entered. Claims 32, 38, 41 and 42 have been canceled. Claims 43-46 have been added. Claims 1, 4, 5, 7, 8, 30, 31, 33-35, 37, 39, 40 and 43-46 are pending and under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

The effective filing date for claims 1, 4, 5, 7, 8, 30, 31, 33-35, 37, 39, 40 and 43-46 is 8-4-97.

Claim Rejections - 35 USC § 112

The rejection of claims 32, 38, 41 and 42 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of culturing avian PGCs comprising maintaining the avian PGCs for at least 14 days in culture comprising (i) isolating a pure population of PGCs from an avian; and (ii) culturing the pure population of PGCs in media comprising LIF, bFGF, IGF and SCF in amounts sufficient to maintain said PGCs for at least 14 days in tissue culture, does not reasonably provide enablement for culturing the PGCs for at least

14 days in media comprising "growth factors in amounts sufficient to maintain said PGCs for at least 14 days" as broadly claimed has been withdrawn because the claims have been canceled.

The rejection of claims 41 and 42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn because the claims have been canceled.

1. Claims 44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While it appears that PGC clumps eventually form a monolayer from pg 22, line 1. However, the specification does not define when a "clump" forms a monolayer. It cannot be determined if "PGCs form a monolayer" is limited to a culture with no clumps and only a monolayer or if the phrase encompasses "clumps" that begin to spread out to form a monolayer. The clumps, or embroid bodies, are attached to the tissue culture dish and inherently have some random PGCs that attach to the tissue culture dish (see photos of CEC in culture by Pain - Fig. 1B, Fig. A-D). How many PGCs must be attached to the tissue culture dish for a culture to be considered to have formed a monolayer?

Double Patenting

The rejection of claims 1, 4, 5, 30, 31, 33, 37, 39 and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S.

Patent No. 6,156,569, Dec. 5, 2000, has been withdrawn in view of the terminal disclaimer filed 3-3-03.

The rejection of claims 1, 4, 5, 7, 8, 30, 31, 33, 34, 35, 37, 39 and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,156,569, Dec. 5, 2000 in view of Pain (Pain et al., 1996, Development, Vol. 122, pages 2339-2348) has been withdrawn in view of the terminal disclaimer filed 3-3-03.

The provisional rejection of claims 1, 4, 5, 7, 8, 30, 31, 33-35, 37, 39 and 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-23 and 25-30 of copending Application No. 09/127738 as supported by Pain of record (pg 2340, col. 1, line 9; page 2340, col. 1, 4th and 5th full paragraphs; page 2345, col. 2, line 10) and Simkiss of record (1994, MacLean, ed., Animals with novel genes, Transgenic birds, Cambridge Univ. Press, Cambridge England, NY, NY, pages 106-137; page 111, Fig. 4.1, top panel) has been withdrawn in view of the terminal disclaimer filed 3-3-03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 4, 5, 7, 8, 30, 31, 33-35, 37, 39, 40 and 43-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Pain (1996, Development, Vol. 122, pg 2339-2348).

Pain taught culturing chicken PGCs for 160 days in media comprising LIF, bFGF, SCF and IGF (pg 2340, col. 1, line 9, ESA medium; para. bridging pg 2345-2346). The amounts of growth factors used by Pain were at least the "minimal amounts" in claim 30 (pg 2340, col. 1, line 9). The PGCs inherently form a monolayer because the culture conditions used by Pain are equivalent to those used in the instant invention and because Pain taught the embroid bodies were allowed to attach in culture (pg 2340, col. 2, "Development of embroid bodies *in vitro*"). The reference was received in the library on Aug. 22, 1996; therefore, the rejection is a 102(a).

3. Claims 1, 4, 5, 7, 8, 30, 31, 33-35, 37, 39, 40 and 43-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Samarut (US Patent 6,114,168, Sept. 5, 2000; 102(e) date May 12, 1997).

Pain taught culturing chicken PGCs for 5 weeks in media comprising LIF, bFGF, SCF and IGF (col. 8, line 30; col. 12, line 13). The amounts of growth factors used by Pain were at least the "minimal amounts" in claim 30. The PGCs inherently form a monolayer because the

culture conditions used by Pain are equivalent to those used in the instant invention and because Pain taught the "clumps" of cells become widely spread out and homogenous - features of a monolayer (col. 12, line 8).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

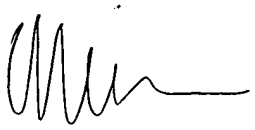
Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER